REMARKS

I. Request for Consideration of a Previously Submitted Supplemental Information Disclosure Statement

On May 27, 2004 Applicants submitted an Information Disclosure Statement and PTO Forms PTO/SB/08A and PTO/SB/08B to disclose six references. Applicants did receive a stamped postcard acknowledging the U.S. Patent and Trademark Office's receipt of the Supplemental IDS. However, in the Examiner's communication of July 21, 2004 there is no indication that the Supplemental IDS was either received or reviewed. Applicants respectfully request the Examiner's consideration of the Supplemental IDS and entry into the record.

II. Discussion of the Rejection under 35 U.S.C. Sec. 103(a) over Lundberg

Claims 1, 2, 4-7 and 13-21 stand rejected under 35 U.S.C. Sec. 103(a) as allegedly unpatentable over Lundberg (U.S. Patent No. 6,132,770). Applicants respectfully traverse the rejection.

As Applicants indicated in their previous response, the tablets of the '770 patent dissolve in a glass of water, not in a patients' mouth. Those skilled in the art understand this, and would not look to a reference directed to effervescent tablets for direction when contemplating creation of preparations for buccal dissolution. This is so because an effervescent tablet will be dissolved in a large amount of water, while a bucally disintegrable tablet will be dissolved in only a minimal amount of water (saliva).

The Examiner does not appear to understand this fact, and has insisted that "the burden is shifted to applicant to submit data showing that the effervescent dosage form of Lundberg does not exhibit the buccal disintegration time being claimed".

Moreover, the Examiner believes that there is "nothing in Lundberg indicating that the effervescent tablet will not disintegrate in a patient's mouth." The teaching of Lundberg would be read and understood by those skilled in the art of pharmaceutical formulations in light of their

knowledge of proper use of specific dosage forms, such as how to adminster an effervescent tablet. The effervescent dosage form is not for ingestion directly in the mouth. An effervescent dosage form would not be considered by one skilled in the art of pharmaceutical formulations to be useful for buccal administration.

To show the Examiner what pharmaceutical formulators understand implicitly, Applicants have provided a Declaration which accompanies this response. In the Declaration, Applicants have calculated the amount of CO_2 which would be evolved in the unlikely event that the tablets of Lundberg were ingested buccally. In the Declaration, Mr. Shimizu has calculated the amount of CO_2 which would be evolved from the tablets formed in Lundberg's Examples 1 and 3-6. The amount of CO_2 which would be evolved in a patient's mouth would be from 100-300 ml. (should the patient directly ingest an effervescent tablet). This is a very large amount of CO_2; an amount which would be prohibitively uncomfortable to a patient ingesting an effervescent tablet bucally.

To prove to the Examiner that this is so, an experiment with human volunteers was performed. The volunteers tested effervescent constituents wherein from 10-100 ml CO_2 would be evolved in the oral cavity, to see what amount of CO_2 they could tolerate. In the test, every volunteer indicated that constituents effervescing 100 ml of CO_2 directly in the mouth were intolerable. This amount of CO_2 is less than the amount calculated to be released from tablets of Lundberg's Example 1; which would theoretically evolve the lowest amount of CO_2 of the exemplified Lundberg effervescing tablets. The other examples of the cited art would evolve even three times more CO_2 in the oral cavity. Effervescent tablets such as those of the cited art which cause such a large amount of CO_2 to be released in the mouth would definitely be too uncomfortable to ingest bucally.

In fact, the volunteers found that constituents from which as little as 20 ml of CO_2 evolved in the mouth to be intolerable. It is quite clear that the Lundberg effervescent tablets cannot be administered directly into the mouth. They are meant to be dissolved in water.

Independent claim 1 recites rapidly disintegrable solid preparations which are bucally dissolved. The tablets of the cited art are not buccally disintegrable, as the amount of effervescence they produce when administered in the mouth is intolerable. Therefore, the cited reference does not teach or suggest Applicants' invention as set forth in claim 1.

Claims 2, 4-7 and 13-17 depend upon claim 1. Applicants submit that the more specific dependent claims are also unobvious for the reason provided above.

Independent claim 21 is directed to tablets, while independent claims 18-20 are directed to methods. In each of these claims, a specific range of buccal dissolution time is recited. As explained in the preceding paragraphs, the cited art does not teach or suggest the methods or tablets which are buccally dissolved.

Therefore Applicants respectfully request withdrawal of the 35 U.S.C. Sec. 103(a) over Lundberg.

III. Acknowledgement of the Allowable Claims

Applicants hereby acknowledge the Examiner's indication of the allowability of claims 9-11. However, Applicants respectfully request that the patentability of these claims be confirmed upon consideration of the May 27, 2004 Supplemental Information Disclosure Statement discussed in Sec. I. above.

IV. Conclusion

Reconsideration and allowance of the claims is requested in light of the arguments provided above. Should the Examiner believe that a conference with Applicants' attorney would advance prosecution of this application, she is respectfully requested to call Applicants' attorney at (847) 383-3391.

Respectfully submitted,

Dated: October 14, 2004

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